BIOLABO
www.biolabo.fr
MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

ALT GPT (IFCC)

Reagent for quantitative determination of Alanine amino transferase activity (ALT) [EC 2.6.1.2] in human serum and plasma

REF K1507	**R1** 2 x 16 mL	**R2** 1 x 8 mL
REF K2507	**R1** 2 x 32 mL	**R2** 2 x 8 mL
REF K4507	**R1** 2 x 40 mL	**R2** 1 x 20 mL

TECHNICAL SUPPORT AND ORDERS
Tel: (33) 03 23 25 15 50
support@biolabo.fr
Latest revision: www.biolabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
I It allows the quantification of global activity of the alanine amino transferase (ALT) enzyme in human serum and plasma.

GENERALITIES (1) (2)

ALT is present in very high amounts in liver and kidney, and in smaller amounts in skeletal muscle and heart. Although serum levels of both AST and ALT become elevated whenever diseases process affecting liver cells integrity, ALT is the more liver-specific enzyme.
A serum elevation of ALT activity is rarely observed in conditions other than parenchymal liver disease (cirrhosis, carcinoma, hepatitis, obstructive jaundice or liver stroke).

PRINCIPLE (4) (5) (6)

Method developed by Wrobleski and La Due, optimised by Henry and Bergmeyer (following modified IFCC recommendations). Reaction scheme is as follows:

L- Alanine + 2-Oxoglutarate $\xrightleftharpoons{ALT}$ Pyruvate + L-Glutamate

Pyruvate + NADH + H^+ $\xrightarrow{LDH}$ L-Lactate + NAD^+

The decrease in absorbance proportional to ALT activity in the specimen, is measured at 340 nm.
Absence of P_5P allows a better stability of working reagent.

REAGENTS COMPOSITION

R1 **AL2**	Buffer enzymes	
L-Alanine	700	mmol/L
LDH	≥ 2500	UI/L
EDTA	6	mmol/L
Tris Buffer	135	mmol/L
pH at 30°C	7.50 ± 0.1	
Stabilizer		

R2 **AL2**	Coenzyme	
Tris Buffer	20	mmol/L
NADH	≤ 1.4	mmol/L
2-Oxoglutarate	80	mmol/L
Stabilizer		

According to 1272/2008/EC Regulation, these reagents are not classified as dangerous

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

I Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Ready for use.

STABILITY AND STORAGE

Stored away from light, well cap in the original vial at 2-8°C, reagents are stable when stored and used as described in the insert:

Unopened,
- Until the expiry date stated on the label of the Kit.

Once opened:
- 2 separated reagents are stable 6 months
- Discard any reagent if cloudy or if blank reagent at 340nm < 1.000.

SPECIMEN COLLECTION AND HANDLING (2) (7)

Unhemolysed serum. Do not use heparinised plasma.

ALT is stable in serum or plasma for:
- 24 hours at room temperature.
- 7 days at 2-8°C.

LIMITS (3) (6)

LDH contained in reagent allows, during pre-incubation step, the reduction of endogenous pyruvate which would positively interfere.
Elevated ALT level may involve NADH depletion during pre-incubation stage, which may lead to under-estimated results.
In case of lipemic or icteric specimens, increased absorbance may mask this phenomenon. It's recommended to check these specimens diluted (1 + 4) in saline solution.

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer Kenza One, Kenza 240TX/ISE or Kenza 450TX/ISE

REFERENCE INTERVALS (2)

	(IU/L) 37°C
Newborns, Infants	13-45
Men	10-40
Women	7-35

Each laboratory should establish its own normal ranges for the population it serves.

PERFORMANCES

On Kenza One, 37°C, 340 nm.

Linearity Range: between 18 and 500 IU/L

Detection limit: approx. 3 IU/L

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (IU/L)	20	59	211
S.D. IU/L	0.9	1.3	1.8
C.V. %	4.2	2.3	0.8

Between run N = 20	*Low level*	*Normal level*	*High level*
Mean (IU/L)	22	60	213
S.D. IU/L	1.2	1.9	4.3
C.V. %	5.3	3.2	2.0

Analytical sensitivity: approx. 0.0054 abs/min for 10 IU/L

Interferences:

Total bilirubin	Negative interference from 219 µmol/L
Direct bilirubin	No interference up to 492 µmol/L
Ascorbic acid	No interference up to 2500 mg/dL
Glucose	No interference up to 1120 mg/dL
Turbidity	Positive interference from 0.143 OD
Haemoglobin	Positive interference from 209 µmol/L

Other substances may interfere (see § Limits)

On the board stability: 2 separate reagents are stable 30 days.

Calibration Frequency: 30 days

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

Comparison studies on Kenza 240TX with commercially available reagent:
Realised on human specimens (n=100) between 5 and 400 IU/L

y = 0.9900 x + 0.2592 r = 0.9985

Performances and stability data on Kenza 450TX/ISE and Kenza 240TX/ISE are available on request

CALIBRATION

- REF 95015 Multicalibrator traceable *to ERM-AD454k*

The calibration frequency depends on proper instrument functions and on the preservation of reagent.

QUALITY CONTROL

- REF 95010 EXATROL-N Level I
- REF 95011 EXATROL-P Level II
- External quality control program

It is recommended to control in the following cases:

- At least once a run
- At least once within 24 hours
- When changing vial of reagent
- After maintenance operations on the instrument

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Refer to validated application of the Kenza Analyzer used

CALCULATION

The analyzer provides directly result in IU/L.
Refer to the instruction of use of Kenza analyzer.

REFERENCES

(1) *TIETZ N.W. Textbook of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 652-657*
(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 64-67*
(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-6 to 3-16.*
(4) *HENRY R. J. andt al., Am J clin Path (1960), 34, 398*
(5) *Bergmeyer HU.,and al. Clin. Chem. (1978), 24, p.58-73*
(6) *IFCC Method for L-Alanine aminotransferase. J Clin. Chem., Clin. Biochem.(1986), 24, p.481-495).*
(7) *MURRAY RL., « Alanine aminotransironase » in clinical chemistry. Theory, analysis, and correlation.Kapan LA, Pesce AJ, (Eds), CV Mosby St Louis (1984): 1090*

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with